IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC., Plaintiffs, v. CIPLA LIMITED, et al., Defendants.	C.A. No. 18-192 (CFC) (CJB) (Consolidated) **CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**
PHARMACYCLICS LLC and JANSSEN BIOTECH, INC., Plaintiffs, v. ALVOGEN PINE BROOK LLC and NATCO PHARMA LTD., Defendants.	C.A. No. 19-434 (CFC) (CJB) **CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**

JOINT [PROPOSED] PRETRIAL ORDER

Plaintiffs Pharmacyclics LLC ("PCYC") and Janssen Biotech, Inc. ("Janssen") (collectively "Plaintiffs") and Defendants Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively "Alvogen"); Zydus Worldwide DMCC and Cadila Healthcare Limited (collectively "Zydus"); and Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively "Sandoz") (all collectively, "Defendants"), by

their undersigned counsel, collectively submit this proposed Joint Pretrial Order pursuant to D. Del. L.R. 16.3. The parties attempted in good faith to reach consensus on the following issues. To the extent the parties had differing positions, each parties' respective proposal is explained for the Court's consideration. A Pretrial Conference in this matter is scheduled for September 23, 2020 at 4:30 PM. A **bench (non-jury)** trial has been scheduled to commence before the Honorable Colm F. Connolly on **October 13, 2020**.

Plaintiffs' Counsel: Plaintiffs are represented by Jack B. Blumenfeld (JBlumenfeld@MNAT.com) and Jeremy A. Tigan (JTigan@MNAT.com) of Morris, Nichols, Arsht & Tunnell LLP, 1201 North Market Street, P.O. Box 1347, Wilmington, DE 19899, (302) 658-9200.

Pharmacyclics' Counsel: Pharmacyclics is represented by Christopher N. Sipes (csipes@cov.com), Erica N. Andersen (eandersen@cov.com), Brianne Bharkhda (bbharkhda@cov.com), and Chanson Chang (cchang@cov.com) of Covington & Burling LLP, One CityCenter, 850 10th St. NW, Washington, DC 20010; and Alexa R. Hansen (ahansen@cov.com) of Covington & Burling LLP, Salesforce Tower, 415 Mission Street, Suite 5400, San Francisco, CA 94105.

Janssen's Counsel: Janssen is represented by Irena Royzman (iroyzman@kramerlevin.com) and Christine Willgoos (cwillgoos@kramerlevin.com) of Kramer Levin Naftalis & Frankel LLP, 1177

Avenue of the Americas, New York, NY 10036, (212) 715-9100, and Hannah Lee (hlee@kramerlevin.com) of Kramer Levin Naftalis & Frankel LLP, 990 Marsh Road, Menlo Park, CA 94025.

Defendants' Counsel:

Alvogen's Counsel: Alvogen is represented by Melanie K. Sharp (msharp@ycst.com), James L. Higgins (jhiggins@ycst.com), Steven W. Lee (slee@ycst.com) of Young Conaway Stargatt & Taylor LLP, 1000 North King Street, Wilmington, DE 19801, and Siegmund Y. Gutman (sgutman@proskauer.com), David M. Hanna (Dhanna@proskauer.com), Michelle M. Ovanesian (movanesian@proskauer.com), and Christopher D. Lynch (clynch@proskauer.com) of Proskauer Rose LLP, 2029 Century Park East, Suite 2400, Los Angeles, CA 90067-3010, and Kimberly Q. Li (kli@proskauer.com) of Proskauer Rose LLP, One International Place, Boston, MA 02110-2600.

Zydus's Counsel: Zydus is represented by David E. Moore (dmoore@potteranderson.com), Bindu A. Palapura (bpalapura@potteranderson.com), and Stephanie E. O'Byrne (sobyrne@potteranderson.com) of Potter Anderson & Corroon LLP, Hercules Plaza, 6th Floor, 1313 N. Market Street, Wilmington, DE 19801, and Jayadeep R. Deshmukh (jdeshmukh@kasowitz.com), Trevor J. Welch (twelch@kasowitz.com), Hershy Stern (hstern@kasowitz.com), Joshua Whitehill

(jwhitehill@kasowitz.com), Jayita Guhaniyogi (jguhaniyogi@kasowitz.com), and M. Diana Danca (mdanca@kasowitz.com) of Kasowitz Benson Torres LLP, 1633 Broadway, New York, NY 10019.

Sandoz's Counsel: Sandoz is represented by Dominick T. Gattuso (dgattuso@hegh.law) of Heyman Enerio Gattuso & Hirzel LLP, 300 Delaware Avenue, Suite 200, Wilmington, DE, and Natalie C. Clayton (natalie.clayton@alston.com), and Madeline E. Byrd (maddy.byrd@alston.com) of Alston & Bird LP, 90 Park Avenue, 15th Floor, New York, NY 10016-9400, and Shri M. Abhyankar (shri.abhyankar@alston.com) of Alston & Bird LP, One Atlantic Center, 1201 West Peachtree Street, Suite 4900, Atlanta, GA 30309-3424.

I. NATURE OF THE CASE AND PLEADINGS

A. Nature of the Actions

1. These actions for patent infringement (C.A. No. 18-192, C.A. 19-434), arise under the patent laws of the United States, Title 35, and are brought pursuant to the Hatch-Waxman Act, arising out of the filing by each of Defendants Alvogen, Zydus, and Sandoz with the U.S. Food & Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA"), seeking approval for generic versions of either Plaintiffs' IMBRUVICA® Tablets (Alvogen) or Capsules (Sandoz and Zydus), pursuant to 21 U.S.C. § 355(j) prior to the expiration of one or more of the following patents: U.S. Patent Nos. 8,008,309 ("the '309 Patent") (Alvogen,

Zydus); 8,697,711 ("the '711 Patent") (Alvogen, Zydus); 8,754,090 ("the '090 Patent") (Alvogen, Zydus); 9,795,604 ("the '604 Patent") (Sandoz); 9,725,455 ("the '455 Patent") (Alvogen); 9,296,753 ("the '753 Patent") (Alvogen); 10,106,548 ("the '548 Patent") (Alvogen, Zydus, Sandoz); 10,294,231 ("the '231 Patent") (Sandoz), 10,125,140 ("the '140 Patent") (Alvogen); 9,655,857 ("the '857 patent") (Alvogen); and 10,213,386 ("the '386 Patent") (Alvogen)[1].

2. Pharmacyclics is the assignee of the '309, '711, '091, '090, '753, '455, '604, '140, '548, '857, '386, and '231 Patents, and those patents have been listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations,* also known as the "Orange Book." Janssen is the exclusive licensee with respect to each of the patents.

3. The label for IMBRUVICA® indicates that IMBRUVICA® is a kinase inhibitor and that ibrutinib covalently binds with a cysteine residue in the active site of the protein Bruton's tyrosine kinase ("BTK"). IMBRUVICA® is indicated for the treatment of patients with mantle cell lymphoma ("MCL") who

[1] In an effort to streamline this case, Plaintiffs are no longer asserting certain claims against certain Defendants and are no longer asserting the following patents against any Defendant: U.S. Patent Nos. 7,514,444 ("the '444 Patent"); 8,754,091 ("the '091 Patent"); 8,476,284 ("the '284 Patent"); 8,497,277 ("the '277 Patent"); 8,735,403 ("the '403 Patent"); 8,952,015 ("the '015 Patent"); 8,957,079 ("the '079 Patent"); 9,181,257 ("the '257 Patent"); 9,713,617 ("the '617 Patent"); 10,010,507 ("the '507 Patent"); 10,294,232 ("the '232 Patent").

have received at least one prior therapy, chronic lymphocytic leukemia ("CLL")/small lymphocytic lymphoma ("SLL"), CLL/SLL with 17p deletion, Waldenström's macroglobulinemia ("WM"), marginal zone lymphoma ("MZL") who require systemic therapy and have received at least one prior anti-CD20-based therapy, chronic graft versus host disease ("cGVHD") after failure of one or more lines of systemic therapy. Plaintiffs sell in the United States Imbruvica Capsules pursuant to New Drug Application ("NDA") No. 205552 and Imbruvica Tablets pursuant to NDA No. 210563, which have been approved by the FDA.

4. Alvogen served Plaintiffs with a Notice Letter dated January 16, 2019 ("Alvogen's First Notice Letter") that provided written notice to Plaintiffs that Alvogen had submitted ANDA No. 212763 to the FDA seeking approval for a proposed generic version of IMBRUVICA® tablets in 140 mg, 280 mg, 420 mg, and 560 mg dosage strengths that included a Paragraph IV certification for each of the '309, '711, '090, '455, '548, '753, '140, and '857 Patents, among other patents. Alvogen served Plaintiffs a second Notice Letter dated April 26, 2019 ("Alvogen's Second Notice Letter") that provided written notice to Plaintiffs that Alvogen had submitted a Paragraph IV certification in its ANDA No. 212763 for the '386 Patent.

5. Alvogen's ANDA No. 212763 seeks FDA approval to engage in the commercial manufacture, use or sale of ibrutinib tablets in 140 mg, 280 mg, 420 mg, and 560 mg dosage strengths as generic versions of IMBRUVICA® Tablets

("Alvogen's ANDA Product") prior to the expiration of the '309, '711, '090, '455, '548, '753, '140, '857, and '386 Patents ("Alvogen Asserted Patents").

6. Zydus served Plaintiffs with a Notice Letter dated January 3, 2018 ("Zydus's First Notice Letter") that provided written notice to Plaintiffs that Zydus had submitted ANDA No. 211344 to the FDA seeking approval for a proposed generic version of IMBRUVICA® capsules in 140 mg dosage strength that included a Paragraph IV certification for each of the '309, '711, and '090 Patents, among other patents. Zydus served Plaintiffs a second Notice Letter dated December 6, 2018 ("Zydus's Second Notice Letter") that provided written notice to Plaintiffs that Zydus had submitted a Paragraph IV certification for, *inter alia*, the '548 Patent in its ANDA No. 211344 for a proposed generic version of IMBRUVICA® capsules in 140 mg dosage strength. Zydus served Plaintiffs a third Notice Letter dated December 14, 2018 ("Zydus's Third Notice Letter") that provided written notice to Plaintiffs that Zydus had submitted a Paragraph IV certification for each of the '309, '711, '090, and the '548 Patents, among others, in its ANDA No. 211344 for a proposed generic version of IMBRUVICA® capsules in 70 mg dosage strength.

7. Zydus's ANDA No. 211344 ("Zydus's ANDA") seeks FDA approval to engage in the commercial manufacture, use, or sale of ibrutinib capsules in 70 mg and 140 mg dosage strengths as generic versions of IMBRUVICA®

Capsules ("Zydus's ANDA Product") prior to the expiration of the '309, '711, '090, and '548 Patents ("Zydus Asserted Patents").

8. Sandoz served Plaintiffs with a Notice Letter dated January 3, 2018 ("Sandoz's First Notice Letter") that provided written notice to Plaintiffs that Sandoz had submitted ANDA No. 211267 to the FDA seeking approval for proposed generic version of IMBRUVICA® capsules in 140 mg dosage strength that included a Paragraph IV certification for the '604 Patent, among other patents. Sandoz also served Plaintiffs with a second Notice Letter dated February 15, 2019 that represented that Sandoz had submitted a Paragraph IV certification for the '548 Patent ("Sandoz's Second Notice Letter"), among other patents. Sandoz sent Plaintiffs a third Notice Letter dated August 7, 2019 representing that Sandoz had submitted a Paragraph IV certification for the '231 Patent ("Sandoz's Third Notice Letter").

9. Sandoz's ANDA No. 211267 ("Sandoz's ANDA") seeks FDA approval to engage in the commercial manufacture, use, or sale of ibrutinib capsules in 140 mg dosage strength as generic versions of IMBRUVICA® Capsules ("Sandoz's ANDA Product") prior to the expiration of the '604, '548, and '231 patents ("Sandoz Asserted Patents").

10. As detailed below, the operative pleadings in C.A. No. 18-192 are Plaintiffs' Second Amended Complaint For Patent Infringement Against Zydus

and Sandoz (D.I. 220), Zydus's Answer to Plaintiffs' Second Amended Complaint (D.I. 225), Plaintiffs' Answer to Zydus's Second Amended Counterclaims (D.I. 237), Sandoz's Answer and Counterclaims to Plaintiffs' Second Amended Complaint (D.I. 227), and Plaintiffs' Answer to Sandoz's Counterclaims to Plaintiffs' Second Amended Complaint (D.I. 249).

11. The operative pleadings in C.A. No. 19-434 are Plaintiffs' First Amended Complaint (D.I. 14), Alvogen's Answer to Plaintiffs' First Amended Complaint (D.I. 21), Natco's Answer to Plaintiffs' First Amended Complaint (D.I. 22), Plaintiffs' Answer to Alvogen's First Amended Counterclaims (D.I. 26), and Plaintiffs' Answer to Natco's First Amended Counterclaims (D.I. 27).

B. Plaintiffs' Claims

1. Causes of Action Against Alvogen (C.A. No. 19-434-CFC)

12. Plaintiffs' First Amended Complaint (D.I. 14) alleges that Alvogen's filing of its ANDA No. 212763 constitutes an act of infringement of the '309, '711, '090, '753, '857, '455, '548, '386, and '140 Patents, among other patents, under 35 U.S.C. § 271(e)(2)(A) and/or §§ 271(a), (b), or (c). The asserted claims of the Alvogen Asserted Patents are Claim 10 of the '309 Patent; Claim 1 of the '711 Patent; Claim 2 of the '090 Patent; Claims 5, 10, and 12 of the '455 Patent; Claim 17 of the '753 Patent; Claims 18 and 19 of the '548 Patent; Claim 4 of the '140

Patent; Claims 10, 28, 30, and 37 of the '857 Patent; and Claim 2 of the '386 Patent (collectively, the "Alvogen Asserted Claims").[2]

13. Plaintiffs seek a judgment that Alvogen has infringed the Alvogen Asserted Claims under 35 U.S.C. § 271(e)(2)(A).

14. Plaintiffs seek a judgment declaring that the manufacture, use, offer for sale, sale, and/or importation of Alvogen's ANDA Product would constitute infringement of Claim 10 of the '309 Patent; Claim 1 of the '711 Patent; Claim 2 of the '090 Patent; Claims 5, 10, and 12 of the '455 Patent; Claim 17 of the '753 Patent; Claims 18 and 19 of the '548 Patent; Claim 4 of the '140 Patent; Claims 10, 28, 30, and 37 of the '857 Patent; and Claim 2 of the '386 Patent or the inducement of or contribution to such infringement by Alvogen pursuant to 35 U.S.C. §§ 271 (a), (b) and/or (c).

15. Plaintiffs seek a judgment that the Alvogen Asserted Claims are not invalid.

16. Plaintiffs seek a judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Alvogen's ANDA shall be no earlier than the last expiration date of any of the Alvogen Asserted

[2] With respect to Alvogen, Plaintiffs are not seeking a determination of infringement for, nor any requested relief in conjunction with, any claims or patents other than the Alvogen Asserted Claims.

Patents, or any later expiration of exclusivity of the Alvogen Asserted Patents, including any extensions or regulatory exclusivities.

17. Plaintiffs seek a judgment permanently enjoining Alvogen and each of its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons in active concert with them, from commercially manufacturing, selling or offering for sale, using, or importing Alvogen's ANDA Product until the day after the expiration of the Alvogen Asserted Patents, including any additional exclusivity period applicable to the Alvogen Asserted Patents, and from otherwise infringing the claims of the Alvogen Asserted Patents.

18. Plaintiffs seek an award of damages or other relief pursuant to 35 U.S.C. § 271(e)(4)(C), if Alvogen engages in the commercial manufacture, use, offer for sale, sale or importation of Alvogen's ANDA Product, or any product that infringes the Alvogen Asserted Patents, or induces or contributes to such conduct, prior to the expiration of the Alvogen Asserted Patents, including any additional exclusivity period applicable to the Alvogen Asserted Patents.

19. Plaintiffs seek a declaration that this case is exceptional.

20. Plaintiffs seek their costs, expenses, and reasonable attorneys' fees in this action pursuant to 35 U.S.C. §§ 271(e)(4) and 285.

2. Causes of Action Against Zydus (C.A. No. 18-192)

21. Plaintiffs' Second Amended Complaint For Patent Infringement Against Zydus (D.I. 220) alleges that Zydus's filing of its ANDA No. 211344 constitutes an act of infringement of the '309, '711, '090, and '548 Patents, among others, under 35 U.S.C. § 271(e)(2)(A) and §§ 271 (a), (b), (c) and/or (g). The asserted claims of the Zydus Asserted Patents are Claim 10 of the '309 Patent; Claims 1 and 7 of the '711 Patent; Claim 2 of the '090 Patent; and Claims 18 and 19 of the '548 Patent (collectively, the "Zydus Asserted Claims").[3]

22. Plaintiffs seek a judgment that Zydus has infringed the Zydus Asserted Claims under 35 U.S.C. § 271(e)(2)(A).

23. Plaintiffs seek a judgment declaring that the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product would constitute infringement of the Claim 10 of the '309 Patent; Claims 1 and 7 of the '711 Patent; Claim 2 of the '090 Patent; and Claims 18 and 19 of the '548 Patent or the inducement of or contribution to such infringement by Zydus pursuant to 35 U.S.C. §§ 271 (a), (b), (c) and/or (g).

24. Plaintiffs seek a judgment that the Zydus Asserted Claims are not invalid.

[3] With respect to Zydus, Plaintiffs are not seeking a determination of infringement for, nor any requested relief in conjunction with, any claims or patents other than the Zydus Asserted Claims.

25. Plaintiffs seek a judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Zydus's ANDA shall be no earlier than the last expiration date of any of the Zydus Asserted Patents, or any later expiration of exclusivity of the Zydus Asserted Patents, including any extensions or regulatory exclusivities.

26. Plaintiffs seek a judgment permanently enjoining Zydus and each of its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons in active concert with them, from commercially manufacturing, selling or offering for sale, using, or importing Zydus's ANDA Product until the day after the expiration of the Zydus Asserted Patents, including any additional exclusivity period applicable to the Zydus Asserted Patents, and from otherwise infringing the claims of the Zydus Asserted Patents.

27. Plaintiffs seek an award of damages or other relief pursuant to 35 U.S.C. § 271(e)(4)(C), if Zydus engages in the commercial manufacture, use, offer for sale, sale or importation of Zydus's ANDA Product, or any product that infringes the Zydus Asserted Patents, or induces or contributes to such conduct, prior to the expiration of the Zydus Asserted Patents, including any additional exclusivity period applicable to the Zydus Asserted Patents.

28. Plaintiffs seek a declaration that this case is exceptional.

29. Plaintiffs seek their costs, expenses, and reasonable attorneys' fees in this action pursuant to 35 U.S.C. §§ 271(e)(4) and 285.

3. Causes of Action Against Sandoz (C.A. No. 18-192)

30. Plaintiffs' Second Amended Complaint For Patent Infringement Against Sandoz (D.I. 220) alleges that Sandoz' filing of its ANDA No. 211267 constitutes an act of infringement of the '604, '548, and '231 Patents under 35 U.S.C. § 271(e)(2)(A) and §§ 271 (a), (b), and/or (c). The asserted claims of the Sandoz Asserted Patents are Claims 1, 4, 6–10, 13, 15, 24, 28, 29-31, 35, 39, 43, 44–46, 50, 51-53, and 55 of the '604 Patent[4]; Claims 18 and 19 of the '548 Patent; and Claims 18 and 27 of the '231 Patent (collectively, the "Sandoz Asserted Claims").[5]

31. Plaintiffs seek a judgment that Sandoz has infringed the Sandoz Asserted Claims under 35 U.S.C. § 271(e)(2)(A).

32. Plaintiffs seek a judgment declaring that the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would constitute infringement of the Sandoz Asserted Claims or the inducement of or contribution to such infringement by Sandoz pursuant to 35 U.S.C. §§ 271 (a), (b) and/or (c).

[4] The '604 Patent is also subject to an *inter partes* review (IPR2019-865), and a decision is expected from the PTAB next week. Plaintiffs intend to reduce the number of claims once the decision has been issued.

[5] With respect to Sandoz, Plaintiffs are not seeking a determination of infringement for, nor any requested relief in conjunction with, any claims or patents other than the Sandoz Asserted Claims.

33. Plaintiffs seek a judgment that the Sandoz Asserted Claims are not invalid.

34. Plaintiffs seek a judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the last expiration date of any of the Sandoz Asserted Patents, or any later expiration of exclusivity of the Sandoz Asserted Patents, including any extensions or regulatory exclusivities.

35. Plaintiffs seek a judgment permanently enjoining Sandoz and each of its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons in active concert with them, from commercially manufacturing, selling or offering for sale, using, or importing Sandoz's ANDA Product until the day after the expiration of the Sandoz Asserted Patents, including any additional exclusivity period applicable to the Sandoz Asserted Patents, and from otherwise infringing the claims of the Sandoz Asserted Patents.

36. Plaintiffs seek an award of damages or other relief pursuant to 35 U.S.C. § 271(e)(4)(C), if Sandoz engages in the commercial manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product, or any product that infringes the Sandoz Asserted Patents, or induces or contributes to such conduct, prior to the expiration of the Sandoz Asserted Patents, including any additional exclusivity period applicable to the Sandoz Asserted Patents.

37. Plaintiffs seek a declaration that this case is exceptional.

38. Plaintiffs seek their costs, expenses, and reasonable attorneys' fees in this action pursuant to 35 U.S.C. §§ 271(e)(4) and 285.

C. Defendant Alvogen's Answer, Defenses, and Counterclaims

39. On June 24, 2019, Alvogen and Natco filed an Answers, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended Complaint (C.A. 19-434, D.I. 21, 22), denying infringement of the Alvogen Asserted Patents and alleging that the claims of the Alvogen Asserted Patents are invalid. Alvogen and Natco concurrently filed counterclaims seeking a declaration that its ANDA Product would not infringe any valid or enforceable[6] claim of the Alvogen Asserted Patents and that the claims of the Alvogen Asserted Patents are invalid.[7]

40. Alvogen respectfully requests that the Court enter a judgment as follows: (a) that all relief requested by Plaintiffs should be denied; (b) that Alvogen and its ANDA Product have not infringed, are not infringing, and will not infringe,

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[6] **Plaintiffs' Footnote:** Enforceability is not at issue in this litigation.

[7] **Defendants' Footnote:** Alvogen's and Natco's Answers also include counterclaims for non-infringement and invalidity of the '444, '284, '277, '403, '015, '079, '257, '091, and '507 patents, patents which Plaintiffs' First Amended Complaint assert against Alvogen and Natco. Plaintiffs have stated they are not pursuing claims of infringement for the '444, '284, '277, '403, '015, '079, '257, '091, and '507 patents (as well as other claims from the Asserted Patents that are no longer asserted), but have not amended their pleadings to remove these patents and claims. Plaintiffs and Alvogen and Natco are meeting and conferring to decide on a process to formalize Plaintiffs' withdrawal of their assertion of these patents and claims.

either literally or under the doctrine of equivalents, any valid claim of the Alvogen Asserted Claims by the making, use, sale, offer for sale, marketing, or importation into the United States of Alvogen's ANDA Product; (c) that the Alvogen Asserted Claims are invalid; (d) that the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) expire immediately; (e) that this case is exceptional under 35 U.S.C. § 285; (f) that Alvogen be awarded its attorneys' fees, costs, and expenses in this action; and (g) that Alvogen be awarded such other further relief as this Court may deem just and proper.

D. Defendant Zydus's Answer, Defenses, and Counterclaims

41. On September 3, 2019, Zydus filed an Answer to Plaintiffs' Second Amended Complaint for Patent Infringement (C.A. 18-192, D.I. 225), denying infringement of the asserted claims of the Zydus Asserted Patents, and alleging that the claims of those patents are invalid. Zydus concurrently filed counterclaims seeking, among other things, a declaration that is ANDA Product would not infringe any valid claim of the Zydus Asserted Patents and that the claims of the Zydus Asserted Patents are invalid.[8]

[8] **Defendants' Footnote:** Zydus's Answer also included counterclaims for non-infringement and invalidity of the '444, '284, '277, '403, '015, '079, '257, '753, '455, '091, and '140 patents, patents which Plaintiffs' complaints assert against Zydus. Plaintiffs have stated they are not pursuing claims of infringement for the '444, '284, '277, '403, '015, '079, '257, '753, '455, '091, and '140 patents (as well as other claims from the Asserted Patents that are no longer asserted), but have not

42. Zydus respectfully requests that the Court enter a judgment as follows: (a) that all relief requested by Plaintiffs should be denied; (b) that Zydus and Zydus's ANDA Product have not infringed, are not infringing, and will not infringe, either literally or under the doctrine of equivalents, any valid claim of the Zydus Asserted Claims, by the making, use, sale, offer for sale, marketing, or importation into the United States of Zydus's ANDA Product; (c) that the Asserted Claims are invalid; (d) that the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) expire immediately; (e) that this case is exceptional under 35 U.S.C. § 285; (f) that Zydus be awarded its attorneys' fees, costs, and expenses in this action; and (g) that Zydus be awarded such other further relief as this Court may deem just and proper. (C. A. No. 18-192, D.I. 255 at 112-113).

E. Defendant Sandoz's Answer, Defenses, and Counterclaims

43. On September 6, 2019, Sandoz filed an Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' Second Amended Complaint for Patent Infringement (C.A. 18-192, D.I. 227) ("Sandoz's Answer"), denying infringement of any asserted claim of the Sandoz Asserted Patents and alleging that the claims of those patents are invalid. Sandoz concurrently filed counterclaims seeking a

amended their pleadings to remove these patents and claims. Plaintiffs and Zydus are meeting and conferring to decide on a process to formalize Plaintiffs' withdrawal of their assertion of these patents and claims.

declaration that is ANDA Product would not infringe any valid claim of the asserted patents and that the claims of the patents are invalid.[9]

44. Sandoz respectfully requests that the Court enter a judgment as follows: (a) that all relief requested by Plaintiffs should be denied; (b) that Sandoz and its ANDA Product have not infringed, are not infringing, and will not infringe, either literally or under the doctrine of equivalents, any valid claim of the Sandoz Asserted Claims by the making, use, sale, offer for sale, marketing, or importation into the United States of Sandoz's ANDA Product; (c) that the Asserted Claims are invalid; (d) that the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) expire immediately; (e) that this case is exceptional under 35 U.S.C. § 285; (f) that Sandoz be awarded its attorneys' fees, costs, and expenses in this action; and (g) that Sandoz be awarded such other further relief as this Court may deem just and proper. (C. A. No. 18-192, D.I. 227 at 69-70).

[9] **Defendants' Footnote:** Sandoz's Answer also includes counterclaims for non-infringement and invalidity of the '753, '455, '617, '232, and '140 Patents, patents which Plaintiffs' Second Amended Complaint assert against Sandoz. Plaintiffs have stated they are not pursuing claims of infringement for the '753, '455, '617, '232, and '140 Patents (as well as other claims from the Asserted Patents that are no longer asserted), but have not amended their pleadings to remove these patents and claims. Plaintiffs and Sandoz are meeting and conferring to decide on a process to formalize Plaintiffs' withdrawal of their assertion of these patents and claims.

F. Summary of Asserted Claims

45. For the convenience of the Court, the table below identifies the asserted claims:

Patent	Alvogen	Zydus	Sandoz
’309	10	10	
’711	1	1, 7	
’090	2	2	
’604			1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, 55
’455	5, 10, 12		
’753	17		
’548	18, 19	18, 19	18, 19
’231			18, 27
’140	4		
’857	10, 28, 30, 37		
’386	2		

G. Claim Construction

46. The Court issued a Claim Construction Order on February 3, 2020 (C.A. No. 18-192, D.I. 346) in the Capsule Action, where the terms and their constructions that remain applicable to the Capsule Action are as follows:

“**compound**” ’309 Patent ’711 Patent ’091 Patent	“A substance formed when two or more elements are chemically bonded together. These elements cannot be separated by physical means.”

"**A crystalline form of [ibrutinib]**" '548 Patent	No construction necessary—plain and ordinary meaning
"**irreversible Btk inhibitor**" '091 Patent	"inhibitor of Btk that can form a covalent bond with an amino acid residue of Btk"
"**inhibitor of Bruton's tyrosine kinase (Btk)**" '090 Patent	"inhibitor of the enzymatic phosphotransferase activity of Bruton's tyrosine kinase (Btk)"

47. The Court issued a Claim Construction Order on February 3, 2020 (C.A. No. 19-434, D.I. 168) in the Tablet Action, where the terms and their constructions are as follows:

"**compound**" '309 Patent '711 Patent '091 Patent '444 Patent '284 Patent '079 Patent '257 Patent	"A substance formed when two or more elements are chemically bonded together. These elements cannot be separated by physical means."
"**compound**" '857 Patent '507 Patent	"A substance formed when two or more elements are chemically bonded together. These elements cannot be separated by physical means."

"**the structure [. . .]**" '090 Patent '857 Patent '091 Patent '277 Patent '403 Patent '015 Patent	No construction necessary—plain and ordinary meaning
"**pharmaceutical[ly] acceptable [. . .] salt[s] thereof**" '309 Patent '091 Patent '015 Patent '079 Patent '403 Patent '257 Patent '444 Patent	"salt[s] that has/[have] no persistent detrimental effect on the general health of the subject being treated or does/[do] not abrogate the biological activity or properties of the compound, and is/[are] relatively nontoxic"
"**ibrutinib**" '857 Patent '386 Patent '507 Patent	No construction necessary—plain and ordinary meaning
"1-((R)-3-(4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4-d]pyrimidin-1-yl)piperidin-1-yl)prop-2-en-1-one" '309 Patent '455 Patent '753 Patent '548 Patent '140 Patent '444 Patent	No construction necessary—plain and ordinary meaning

"**crystalline form**" '455 Patent '753 Patent '548 Patent '140 Patent	"a solid material whose atoms, molecules, or ions are arranged in a highly ordered structure forming a three-dimensional lattice that extends in all directions"
"[X-ray powder diffraction (XRPD) pattern; Infrared (IR) Spectrum; DSC thermogram; or thermo-gravimetric analysis (TGA) thermograph] as [shown/the one set forth] in [FIG. 1; 2; 3; or 4, respectively]" '753 Patent	No construction necessary—plain and ordinary meaning
"**solid tablet formulation**" '857 Patent '507 Patent	No construction necessary—plain and ordinary meaning
"**mean $AUC_{0-\infty}$ of about 465 ng*h/ml +/- 248 ng*h/ml**" '386 Patent	No construction necessary—plain and ordinary meaning

II. JURISDICTION

48. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Hatch Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, *see* 21 U.S.C. § 355(j). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202. Alvogen and Natco

stated in their Answers that they do not contest personal jurisdiction, or subject matter jurisdiction under 35 U.S.C. § 271(e)(2)(A) for the limited purpose of this action only. (C.A. 19-434, D.I. 21, at ¶¶ 20, 34; D.I. 22 at ¶¶ 20, 35.) Zydus stated in its Answer that it does not contest personal or subject matter jurisdiction for the limited purpose of this action only. (C.A. 18-192, D.I 225 at ¶¶ 28–38.) Sandoz stated in its Answer that it does not contest personal or subject matter jurisdiction for purposes of this action. (C.A. 18-192, D.I. 227 at ¶¶ 28, 42.)

49. Venue is not disputed for purposes of this action.

III. STATEMENT OF ADMITTED FACTS

50. The parties stipulate to the facts listed in the attached **Exhibit 1**. These proposed stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

IV. STATEMENTS OF CONTESTED ISSUES OF FACT

51. Plaintiffs' statement of contested issues of fact is attached as **Exhibit 2**.

52. Alvogen's statement of contested issues of fact is attached as **Exhibit 3A**.

53. Sandoz's statement of contested issues of fact is attached as **Exhibit 3B**.

54. Zydus's statement of contested issues of fact is attached as **Exhibit 3C**.

V. STATEMENTS OF LAW

55. Plaintiffs' statement of law is attached as **Exhibit 4**.

56. Alvogen's statement of law is attached as **Exhibit 5A**.

57. Sandoz's statement of law is attached as **Exhibit 5B**.

58. Zydus's statement of law is attached as **Exhibit 5C**.

VI. EXHIBITS

A. Exhibits

59. Plaintiffs' list of exhibits that they may offer at trial, and Defendants' objections thereto including citations to the Federal Rules of Evidence, except demonstrative exhibits and exhibits used solely for impeachment, are attached as **Exhibit 6**. Plaintiffs' trial exhibits will be identified with PTX numbers.

60. Defendants' list of exhibits and Plaintiffs' objections thereto except demonstrative exhibits and exhibits used solely for impeachment, are attached as **Exhibits 7A (Alvogen), 7B (Sandoz), and 7C (Zydus)**. Defendants' trial exhibits will be identified with DTX numbers.

61. The parties' respective keys to their objection codes are appended at the end of each exhibit list.

62. Subject to the remaining provisions of this Order, no party may add to its exhibit list or use at trial an exhibit not present on its list absent stipulation,

or order of the Court. The parties, however, reserve the right to supplement these exhibit lists, by agreement of the parties or as permitted by the Court upon a showing of good cause. Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted, may be used equally by each party, subject to any limitations as to its admission. The exhibit lists may include exhibits that may not necessarily be offered or introduced into evidence.

63. The parties agree that if either party removes or otherwise withdraws an exhibit from its exhibit list, the other party may amend its exhibit list to include that same exhibit. The parties also agree that the parties may make objections to such exhibit, other than an objection based on untimely listing.

64. The parties agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the listed document or any other listed document.

65. The demonstrative exhibits the parties intend to use at trial do not need to be included on their respective exhibit lists.

66. Exhibits to be used solely for impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used at trial. Such exhibits used solely for impeachment and not included on an exhibit list may not be admitted into evidence.

67. Statements from any request for admission responses, interrogatory responses, or pleadings may be read at trial and need not be included on the exhibit lists.

68. The parties stipulate to the authenticity of each document that on its face appears to be generated by a party, including documents generated by its employees during the course of their employment for a party, and produced in this case by a party. Notwithstanding this stipulation, each party preserves its right to object to the document on any ground other than authenticity.

69. Complete legible copies of documents may be offered and received in evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or in the circumstances it would be unfair to admit the copy in lieu of the original. Legible copies of United States patents and the contents of the Patent and Trademark Office file histories may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections that might be made to the admissibility of certified copies.

70. All exhibits shall be pre-marked with a stamp on the first page, using the following color labels and containing the following prefix identifiers:

a. Plaintiffs' Exhibits (Yellow Labels): PTX (beginning with PTX-001)

b. Defendants' Exhibits (Blue Labels): DTX (beginning with DTX-20001)

71. In the case of trial exhibits that have been previously been marked as a deposition exhibit, to remove duplicates and improve legibility of the exhibits used at trial, the parties agree that the trial exhibit shall be treated as identical to the indicated deposition exhibit regardless of whether it bears a deposition exhibit sticker, unless a genuine question is raised as to whether the trial exhibit and deposition exhibit are identical. The parties also agree that two exhibits that are identical (notwithstanding different Bates numbers) shall be treated as identical, unless a genuine question is raised as to whether the exhibits are identical.

72. The parties will be presenting exhibits electronically and respectfully request access to the courtroom shortly before trial, at the Court's convenience, to test the Court's audio-video equipment and set up their equipment.

73. A party will provide, by electronic mail or FTP, a list of trial exhibits to be used in connection with direct examination (specifically identifying the exhibit in connection with the witness) including as necessary making any physical exhibits available for inspection by 7 p.m. EST two days before their intended use, and objections will be provided no later than 7 p.m. EST the night before their intended use. The parties will meet-and-confer by 9 p.m. EST that same night. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention at the beginning of the day. Failure to comply with these procedures, absent an agreement by the parties and

approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

74. Absent agreement between the parties and approval by the Court, no exhibit will be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. Any party that has used an exhibit with the witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number. Exhibits not objected to that are used with a witness at trial will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony. Nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case.

75. The listing of a document on a party's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing side. Each party reserves the right to object to the relevance of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

76. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. Demonstratives and Summary Exhibits

77. The parties agree that the demonstrative exhibits that the parties intend to use at trial do not need to be included on their respective exhibit lists that are part of this Final Pretrial Order.

78. Plaintiffs' demonstrative exhibits will be identified with PDX numbers, starting with PDX 1.

79. Defendants' demonstrative exhibits will be identified with DDX numbers, starting at DDX 1.

80. By no later than 5 pm EST on the calendar day before opening statements, the parties shall exchange color copies of demonstrative exhibits they intend to use in their respective opening statements. By no later than 7 pm EST that same day, any objections to the demonstrative exhibits shall be served on the other side. By 9 pm EST that day, the parties shall meet and confer to resolve any objections, which if necessary will be raised with the Court before opening statements commence.

81. A party will provide color copies of demonstrative exhibits by electronic mail or FTP to be used in connection with direct examination (specifically identifying the exhibit in connection with the witness) including as necessary making any physical exhibits available for inspection by 7 p.m. EST two days before their intended use, and objections will be provided no later than 7 p.m. EST the night

before their intended use. The parties will meet-and-confer at 9 p.m. EST that same night. If good faith efforts to resolve the objections fail, the party objecting to the demonstrative shall bring its objections to the Court's attention at the beginning of the day. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of a demonstrative exhibit or waiver of objection to the exhibit. If any of the demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing party of the change(s).

82. The party seeking to use a demonstrative exhibit in connection with direct examination will provide a color representation of the exhibit to the other side in PDF or PPT form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side in an appropriate electronic format to view the video or animation. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide by electronic means a color representation as a PDF of 8.5 x 11 copies of the exhibits. For each demonstrative that is based on a document or documents produced or exchanged in discovery in this litigation, each party shall disclose to the other parties, either: (a) on the face of the demonstrative; or (b) in a table or other writing provided at the time the demonstrative is exchanged with the other parties, all documents that form the basis of the demonstrative.

83. These provisions regarding demonstrative exhibits do not apply to demonstratives created during testimony or demonstratives to be used for cross-examination, neither of which need to be provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

VII. WITNESSES

A. Live (By Remote Means) Witnesses

84. Where "live" is used in this Pretrial Order, including in the exhibits attached thereto, it shall mean "by remote means" using the agreed upon video and audio system for the remote trial.

85. Plaintiffs' list of the names of the fact and expert witnesses that they intend to call at trial is attached as **Exhibit 8A**. Defendants' objections to Plaintiffs' witnesses are included in this Exhibit. The *curriculum vitae* of every expert expected to testify for Plaintiffs at the time of trial is attached as **Exhibit 8B**.

86. Alvogen's list of the names of the fact and expert witnesses that it intends to call at trial is attached as **Exhibit 9A**. Sandoz's list of the names of the fact and expert witnesses that it intends to call at trial is attached as **Exhibit 9B**. Zydus's list of the names of the fact and expert witnesses that it intends to call at trial is attached as **Exhibit 9C**. Plaintiffs' objections to any identified witnesses are included in those respective Exhibits. The *curriculum vitae* of every expert expected

to testify for Defendants at the time of trial is appended to each of the respective witness lists.

B. Agreements Regarding Presentation And Identification Of Witnesses

87. The parties will identify by email to the opposing parties the witnesses they intend to call (in the order in which the witnesses will be called), and whether those witnesses will be called live or by deposition, by 7 p.m. EST two calendar days before such witness will be called to testify. For example, if the party expects to conduct the examination on Thursday, notice should be given to the opposing party by 7 p.m. EST on Tuesday. The other parties shall identify any objections to such witness(es) by 7 p.m. EST the following day, and the parties shall meet and confer to resolve any objections by 9 p.m. EST that same evening. If good faith efforts to resolve the objections fail, the party objecting to the witness shall bring its objections to the Court's attention for resolution the next day.

88. A party shall promptly notify the opposing party of any change to the identity of witnesses or the anticipated order of witnesses.

89. The parties agree that fact witnesses will be sequestered for opening statements and the testimony of fact witnesses. The parties agree that expert witnesses need not be sequestered.

90. Except as permitted under Local Civil Rule 43.1 or by express permission of the Court, once tendered for cross an examination no witness shall

communicate with anyone else regarding the substance of the witness's testimony until such time as the witness is excused by the Court from that examination. If the witness will be called to the stand to testify at a later time during the trial, once the witness has completed his or her examination and leaves the stand, that witness can speak with counsel before taking the stand to testify at a later time during the trial.

C. Deposition Designations

91. The deposition testimony that Plaintiffs may offer into evidence is identified in **Exhibit 10**.

92. The deposition testimony that Alvogen may offer into evidence is identified in **Exhibit 12A**. The deposition testimony that Sandoz may offer into evidence is identified in **Exhibit 12B**. The deposition testimony that Zydus may offer into evidence is identified in **Exhibit 12C**.

93. With respect to those witnesses whom the parties have identified in Exhibits 8 and 9 who will be called to testify live at trial, no deposition designations or counter-designations are required. Should a fact witness identified in Exhibits 8 and 9 as testifying live at trial become unavailable, as that term is defined in the Federal Rules of Civil Procedure and Federal Rules of Evidence, the parties may designate specific pages and lines of transcript that they intend to read or play in lieu of the witness's appearance upon reasonable notice. The parties shall

immediately notify each other in the event they have decided not to call a witness to testify live at trial.

94. For the avoidance of doubt, with respect to expert witnesses who served reports in the Capsule and Tablet Actions, no deposition designations or counter designations are allowed. Subject to the preceding paragraph, this pretrial order contains the maximum universe of deposition designations, counter-designations, and objections to admission of deposition testimony. The parties, however, reserve the right to supplement their respective deposition designations, counter-designations, and objections to admission of deposition testimony by agreement by the parties, or as otherwise permitted by the Court upon a showing of good cause.

95. A party's decision not to introduce some or all of the testimony of a witness designated by that party herein shall not be commented upon by the other party at trial.

96. The parties also agree that a party who wishes to call an employee of another party as part of its case-in-chief can do so by deposition, regardless of the availability of the witness to testify live.

97. Each party is entitled to offer testimony designated by any other party (whether as a designation or counter-designation), even if not separately listed on its own deposition designation list. For convenience and sake of brevity, the

parties have listed counter-designations without reference to specific affirmative designations by their opposing parties. A party may designate testimony identified as affirmative testimony in this order as a counter-designation.

98. Unless otherwise agreed between the parties, the party offering deposition testimony (other than for the purpose of impeachment) shall identify the deposition testimony to be offered from previously-exchanged designations by 7 p.m. EST at least four calendar days prior to the testimony being offered into the record. A party may choose not to introduce deposition testimony designated in this Pretrial Order. The party receiving the designations shall inform the opposing party of any objections and any specific pages and lines from that deposition to counter-designate by 7 p.m. EST three calendar days prior to the testimony being offered into the record. To the extent necessary, the designating party will provide the opposing party with any objections to the opposing party's counter-designations by 7 p.m. EST the next day. The parties will thereafter meet-and-confer by 9 pm on the same calendar day. Any issues that remain will be raised orally with the Court before the designations are played; unless the Court requests otherwise, there will be no written submissions to the Court.

99. If deposition testimony is to be presented by video, then the party playing the designated testimony shall also serve the other party with electronic

video clips of all testimony to be played by 7 p.m. EST the calendar day before the witness is to be called at trial.

100. Designated deposition testimony will be offered to the Court as designated testimony that the parties play by video in Court, or have read into the record and will count against the party's trial presentation time. Specifically, any affirmative designations offered by a party will count against that party's trial presentation time whereas any counter-designations by the other party will count against the party who made the counter-designations.

101. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial.

102. When deposition designation excerpts are introduced, all admissible deposition counter-designation excerpts, whether offered by videotape or by transcript, will be introduced in the sequence in which the testimony was originally given. The specific portions of the deposition shall be read or played in page order. If an exhibit is introduced in a deposition designation, the exhibit is admitted into evidence if it is included on the offering party's trial exhibit list and is not otherwise objected to.

103. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with three copies of the transcript

of the designations and counter-designations that will be read or played. The parties shall provide the time to be charged to each party to the Court with the transcripts.

104. The above procedures regarding deposition designations do not apply to portions of deposition transcripts and/or video used for impeachment or cross-examination of a witness. Any deposition testimony may be used at trial for the purpose of impeachment, regardless of whether a party specifically identified that testimony on its list of deposition designations, if the testimony is otherwise competent for such purpose.

D. Objections to Expert Testimony

105. The parties reserve the right to object to the opposing party's proffered expert testimony, including testimony based upon improper legal standards, and/or testimony that was not otherwise disclosed during discovery despite an obligation to do so. Furthermore, Defendants incorporate their objections set forth in Exhibit 9, concerning Plaintiffs' expert witnesses. The parties' objections to certain expert witnesses will be set forth in greater detail in their objections made at the time of trial. The parties agree that the Court should rule at trial on objections to expert testimony as beyond the scope of expert disclosures.

VIII. BRIEF STATEMENT OF WHAT PLAINTIFFS INTEND TO PROVE

106. A brief statement of what Plaintiffs intend to prove in support of Plaintiffs' claims is attached as **Exhibit 13**.

IX. BRIEF STATEMENT OF WHAT DEFENDANTS INTEND TO PROVE

107. A brief statement of what Alvogen intends to provide in support of their claims is attached as **Exhibit 14A**. A brief statement of what Sandoz intends to provide in support of their claims is attached as **Exhibit 14B**. A brief statement of what Zydus intends to provide in support of their claims is attached as **Exhibit 14C**.

X. PHASES OF TRIAL

108. **Plaintiffs' proposal:** Plaintiffs propose that the order of the presentation of evidence will follow the burden of proof as follows:

Phase I	Plaintiffs' Case-in-Chief on Infringement
Phase II	Defendants' Rebuttal on Infringement and Case-in-Chief on Invalidity
Phase III	Plaintiffs' Rebuttal on Invalidity[10]

109. **Defendants' proposal:** Defendants propose that the order of the presentation of evidence shall proceed on a patent family by patent family basis as set forth in the illustrative table below, though not necessarily in the listed order or dates of presentation, and with the understanding that there may be some witnesses

[10] Plaintiffs have proposed three rounds of testimony to ensure the trial is efficient and to streamline issues given that objective indicia is part of Defendants' burden of proof on invalidity. However, if the Court would prefer otherwise, Plaintiffs are amenable to a fourth round specifically limited to Defendants' rebuttal on objective indicia of non-obviousness.

that may need to be taken out of time based on their personal availabilities and schedules. For each patent family, the order of presentation outlined in the table in Plaintiffs' proposal shall apply, with the addition of "Phase IV: Defendants' Rebuttal on Objective Indicia of Non-Obviousness" for each family.

Trial Day	Date	Proposed Order of Proof
1	Tuesday, Oct. 13	Opening Statements Compound Patents (begin)
2	Wednesday, Oct. 14	Compound Patents (conclude)
3	Thursday, Oct. 15	Polymorph Patents (begin)
4	Friday, Oct. 16	Polymorph Patents (conclude) Formulation Patents (begin)
5	Monday, Oct. 19	Formulation Patents (conclude)
6	Tuesday, Oct. 20	MCL Patents (begin)
7	Wednesday, Oct. 21	MCL Patents (conclude) cGVHD Patents (begin)
8	Thursday, Oct. 22	cGVHD Patents (conclude)
9	Friday, Oct. 23	Commercial Success
10	Monday, Oct. 26	Closing Arguments

XI. ADDITIONAL "VIRTUAL TRIAL" PROCEDURES

110. With the approval of the Court, the parties will use a neutral hosting platform for the trial.

111. While providing testimony at trial, no witness shall access any form of communication other than the agreed upon official video or audio feed of the trial vendor. **[Plaintiffs' Additional Proposal:** The parties agree that all fact and expert witnesses will be separated from counsel such that, during his or her testimony, the witness cannot communicate with counsel, either visually, audibly,

or through electronic or written means, except through the video link provided to the Court and all counsel.**]** **[Defendants' Additional Proposal**: The parties agree that all fact and expert witnesses may be present in the same room as counsel, so long as counsel in the room appears visually on the video link provided to the Court and that counsel agree to the same rules and standards as if the counsel were in the Courtroom.**]**

112. The parties agree that apart from the official court reporter, neither side will record any portion of the trial or have any other stenographer transcribe the proceedings.

113. The parties agree that no lawyers will appear in person in the courtroom to make argument or otherwise appear before the Court for purposes of the trial, absent agreement by all parties.

114. Expert witnesses may only have their witness binders and paper copies of their expert reports and deposition transcript in front of them when they testify. Fact witnesses may only have a witness binder of exhibits to be used during their direct testimony. To the extent feasible, paper copies of the cross-examination exhibits will be delivered by counsel for the cross-examining party to the witness' location by the evening before the trial day of the cross-examination, and to the attorney who is conducting the direct examination of such witness, with the understanding that neither the witness nor the examining attorney will open the box

of exhibits until directed to do so during the trial proceeding. No other documents, including notes, are permitted to be accessed by the witnesses during their testimony, unless a cross-examination exhibit is identified after the box of cross-examination exhibits is shipped, in which case the witness will access that document virtually when it is introduced during the trial proceeding.

115. All parties will make every effort to reasonably limit the number of participants of the video session to those who have a need to attend. The participants seen on the screen and not muted during the examination of a witness will be limited to: (1) the Court; (2) the witness; (3) the attorney conducting the direct examination; (4) the attorney conducting the cross-examination; and (5) optionally, the court reporter.

116. **[Plaintiffs' Proposal:** Each party will deliver exhibits to the Court that it anticipates using on direct examination or cross examination in the form of a witness binder before the witness is expected to testify.**] [Defendants' Proposal:** Each party will deliver exhibits to the Court that it anticipates using on direct examination or cross examination in the form of a witness binder before the witness is expected to testify, unless a cross-examination exhibit is identified after the cross-examination exhibits are delivered, in which case the document will be introduced virtually during the trial proceeding and counsel will provide copies of

the cross-examination exhibits to the Court the day the cross-examination exhibit is introduced or the next business day.**]**

XII. AMENDMENTS TO PLEADINGS

117. The parties do not seek to amend the pleadings.

XIII. MOTIONS IN LIMINE

118. Plaintiffs' motions in *limine*, along with Defendant's oppositions, and Plaintiffs' replies, are attached as **Exhibit 15**.

119. Defendants' motions in *limine*, along with Plaintiffs' oppositions, and Defendants' replies, are attached as **Exhibit 16**.

XIV. CERTIFICATION REGARDING SETTLEMENT

120. The parties certify that they have engaged in a good-faith effort to explore the resolution of the controversy by settlement. The parties have been unable to reach agreement.

XV. OTHER MATTERS

121. The Court has entered a Stipulated Protective Order (C.A. 18-192, D.I. 50; C.A. 19-434, D.I. 62) to safeguard the confidentiality of certain of the parties' business and technical information, as well as that of third parties. All outside counsel shall handle such protected information in accordance with the terms of the Protective Order and shall not disclose such Confidential Information to persons not authorized to view such information under the terms of the Protective Order. Nonetheless, the presentation of evidence at trial shall take place in open

court, unless a party specifically requests, and the Court agrees, that the Court be closed to the public during presentation of certain portions of the evidence.

122. It is agreed that any party or non-party whose information is subject to the Protective Order may request that testimony or an exhibit, subject to the Protective Order, be placed under seal and handled in accordance with the Protective Order. With the Court's permission, the parties may request that demonstrative exhibits or evidence potentially reflecting confidential information not be made available to the public. The parties have agreed that the individuals designated as In-House Counsel in accordance with Protective Order, or other In-House Counsel agreed to by the parties, may attend any sealed portion of the trial.

123. Notwithstanding the above, pursuant to certain third party confidentiality obligations under agreement between the parties, subject to the Court's approval, a party may request the Court to seal the Courtroom with respect to highly confidential information of a third party, and such request may include a request for other defendant parties' outside counsel and In-House Counsel to leave (or otherwise be secluded from) the virtual Courtroom during such sealed portion of the trial in which such third party evidence is presented.

124. The trial will be timed, and the trial time will be equally divided, with half of the time allocated to Plaintiffs and half of the time allocated to Defendants. Unless otherwise ordered, time will be charged to a party for its opening

statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, any closing argument, and all sides' argument on any motions or objections a party raises to another party's exhibits and demonstrative exhibits.

125. The Courtroom Deputy will keep a running total of trial time used by counsel. If any party uses all of its allotted trial time, the Court will terminate that party's trial presentation.

A. Plaintiffs' Issues[11],[12]

126. Defendants' failure to provide an appropriate stipulation of infringement, or admit the fact of infringement, for asserted claims to which they did not submit a non-infringement expert report:

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[11] Defendants note that Plaintiffs included these four pages of argumentative "Plaintiffs' Issues" for the first time at 2 PM ET of the Pretrial Order deadline. In view of this timing, Defendants did not have sufficient time to respond. In addition to "Plaintiffs' Issues" being inappropriately argumentative, Defendants believe that Plaintiffs' statements in these paragraphs are highly misleading and inaccurate (e.g., Plaintiffs grossly exaggerates the number and scope of Defendants' invalidity defenses), and will be prepared to address the issues raised in those paragraphs with the Court at the pre-trial conference. In the meantime, as Defendants have informed Plaintiffs, Defendants are coordinating to narrow their invalidity defenses and expert testimony before trial.

[12] Plaintiffs provided these issues to Defendants on Monday, September 14; met and conferred with Defendants for four hours on Wednesday, September 16; provided additional requested detail after the meet and confer; and informed Defendants they would include all such issues in the Pretrial Order absent cooperation. Defendants did not respond. Throughout the course of fact and expert discovery, Plaintiffs have asked Defendants to stipulate to infringement where appropriate and to reduce the number of invalidity theories at issue in this litigation.

Claim/Patent	Alvogen	Sandoz	Zydus
Claim 10 of the '309 Patent	X		X
Claim 7 of the '711 Patent			X
Claim 2 of the '090 Patent	X		X
Claim 18 of the '231 Patent		X	
Claim 27 of the '231 Patent		X	
Claim 4 of the '140 Patent	X		
Claim 18 of the '548 Patent	X		
Claim 19 of the '548 Patent	X		
Claim 5 of the '455 Patent	X		
Claim 12 of the '455 Patent	X		

127. Defendants' pursuit of non-infringement defenses that are contrary to law and/or the Court's claim construction orders:

- **'548 Patent (Zydus and Sandoz)**: Non-infringement theory is solely based on lost claim construction position and mischaracterization of Court's construction of crystalline form as Forms A–F. *See* Opposition to Defendants' MIL No. 3.

- **'604 Patent (Sandoz)**: No report contesting direct infringement by physicians and patients, but has not admitted direct infringement. As provided in Plaintiffs' MIL, Sandoz's theory on inducement is contrary to law. *See* Plaintiffs' MIL No. 1.

- **'857 Patent (Alvogen)**: Submitted no rebuttal non-infringement report, but has not admitted that elements are met. The non-infringement theory

in reply report does not compare product to claims. *See* Opposition to Defendants' MIL No. 1.

128. Defendants' use of duplicative experts for invalidity issues:

Duplicative Expert Opinions	Alvogen	Zydus	Sandoz
Compound Patents	Lepore / Swift	Lepore	
'090 Patent (Mantle Cell Lymphoma)	Grossbard	Oleksowicz	
Crystalline Form Patents	Swift/Fassihi	Steed/Stephenson	
Commercial Success	McDuff		Hofmann

129. Defendants assertion of an excessive number of invalidity theories for each claim, and failure to inform Plaintiffs which defenses they intend to pursue at trial. For example, for just three asserted claims, Defendants assert 47 separate invalidity defenses: eleven defenses for Claim 10 of the '309 Patent (one anticipation theory, two obviousness theories, three written description theories, three enablement theories, and two indefiniteness theories); nineteen defenses for Claim 2 of the '090 Patent (four anticipation theories, nine obviousness theories, one written description theory, one enablement theory, two inventorship theories, and two obviousness type double patenting theories); and seventeen defenses for Claim 19 of the '548 Patent (four anticipation theories, four obviousness theories, two written description theories, two enablement theories, one indefiniteness theory, one

improper dependency theory, two obviousness type double patenting theories, and one inventorship theory).

130. Alvogen and Zydus have raised six theories under § 112 (enablement, written description, and indefiniteness) for claim 10 of the 309 Patent in connection with the terms "compound" and "pharmaceutically acceptable salt" that are contrary to the Court's claim construction of these terms. We have identified these theories with particularly to Defendants as they should not be presented at trial.

131. Defendants have included issues in their statements of facts that either were not raised in their expert reports, or have been stricken by Magistrate Judge Burke. We have identified theories with particularity to Defendants as they should not be presented at trial.

132. Sandoz's designation of testimony from an expert (Dr. Koreth, '604 Patent) not in the litigation.

B. Defendants' Issues

133. Plaintiffs' attempt to prevent Defendants from filing appropriate stipulations of infringement with the Court, so that the parties can streamline the number of issues at trial.

134. Plaintiffs' use of duplicative experts for secondary consideration issues related to Compound Patents ('309 Patent, '711 Patent) and Tablet Formulation Patents ('857 Patent, '386 Patent). For example, Drs. Taft and Drover

are offering duplicative testimony with respect to the Tablet Formulation Patents (’857 Patent, ’386 Patent), Drs. Reider and Rule are offering duplicative testimony with respect to the Compound Patents (’309 Patent, ’711 Patent), and Dr. Williams and Rule are offering duplicative testimony with respect to the Tablet Formulation Patents (’857 Patent, ’386 Patent).

135. Plaintiffs are currently asserting 15 claims against Alvogen, 29 claims against Sandoz, and 6 claims against Zydus. Plaintiffs have represented they did not intend to try these numbers of claims against Alvogen, and Sandoz, but refuse to identify the specific claims that they intend to try against Alvogen and Sandoz. Once Plaintiffs identify the specific claims that they intend to try, the invalidity defenses will further narrow, and Defendants are working to see if they can further narrow the invalidity defenses. In fact, Alvogen significantly reduced a number of invalidity defenses across multiple claims and patents on Wednesday, September 16, 2020.

136. Plaintiffs’ refusal to dismiss or otherwise dispose of the claims and patents they are no longer asserting against Defendants.

137. Plaintiffs continued assertion of 25 claims of the ’604 patent against Sandoz.

XVI. ORDER CONTROLS

138. This order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

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